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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,852	02/18/2004	Shinji Yamamori	Q79958	9460
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SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
			EXAMINER	
			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

803

Office Action Summary

Application No.

10/779,852

Applicant(s)

YAMAMORI ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9-12 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5, 9, 17 is/are rejected.
- 7) ☒ Claim(s) 10-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

1. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mick (US Patent 5355893) in view of Phillips (US Patent 6726637).

Regarding claim 1, Mick discloses an airway adapter adapted to be attached to a light emitter of a sensor for detecting carbon dioxide gas in an expired breath comprising an airway case adapted to be disposed below the nostrils of a living body (element 41) and formed with an airway passage extending across an optical axis of a light beam emitted from the sensor's light emitter (41 connects to fitting 25, which communicates with the paths of optical axes corresponding to sensor 70 – see figures 7, 8, and 10); and a mouth guide, adapted to be disposed in front of the living body's mouth so as to define a space communicating with the airway passage (elements 57 and 58 of figure 10, which communicate with the passage via air passage 59 – air enters via the openings visible along surface 58 in figure 10). Mick does not disclose the mouth guide being pivotably supported on the airway case.

Phillips teaches an exhaled carbon dioxide device comprising a mouth guide (element 20) that is pivotally connected (column 3, lines 53-55) to an

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airway passage (element 50), in order to increase the comfort of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mick with the pivotable connection of the mouth guide to the airway case, as taught by Phillips, in order to increase the comfort of the patient.

Regarding claim 17, Mick discloses a device comprising carbon dioxide sensor with a photo emitter and photo receiver (elements 70-73); an airway case that is adapted to be disposed below nostrils of a body and has an airway passage that crosses the light beam of the sensor (elements 41, 19); and a mouth guide that is adapted to be disposed in front of the mouth of the body and create a space that communicates with the airway passage (elements 57-59). Mick does not disclose the mouth guide being pivotably supported on the airway case.

Phillips'637 teaches an exhaled carbon dioxide device comprising a mouth guide (element 20) that is pivotally connected (column 3, lines 53-55) to an airway passage (element 50), in order to increase the comfort of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mick, with the pivotable connection of the mouth guide to the airway case, as taught by Phillips'637, in order to increase the comfort of the patient.

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2. Claims 2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mick in view of Phillips, as applied to claim 1 above, and further in view of Cannon (US Patent Application Publication 2004/0003816).

Regarding claim 2, Mick in view of Phillips discloses all the elements of the current invention, except for the mouth guide comprising a shaft member that is fitted into a hole in the airway case so that the mouth guide may pivot about the hole.

Cannon discloses a device comprising a mouth guide (element 12) and a shaft (element 24), wherein the shaft of the mouth guide is inserted into a hole in order to allow the mouth guide to pivot (Figure 1; paragraph [0023]), in order to increase the patient's comfort, since pivoting around a shaft is well known in the art. The examiner notes that the shaft of Cannon is not integrally molded as part of the mouth guide; however, the final product has the same structure, regardless of the method of formation, and therefore is not patentably distinguishable (see MPEP §2113). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mick in view of Phillips, and comprised the pivoting mechanism with a shaft inserted into a hole about which it may pivot, as taught by Cannon, in order to increase the patient's comfort.

Regarding claim 4, Phillips further teaches that the apparatus may be formed of a material such as plastic (column 4, lines 9-10), which may be flexible and therefore allow stretching, so that the positioning of the apparatus may be changed as needed to efficiently capture the patient's exhaled breath. It would

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have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mick in view of Phillips and Cannon, and formed the airway case or mouth guide of an elastic material, as taught by Phillips, in order to allow the position of the apparatus to be changed as needed to efficiently capture the patient's exhaled breath.

Regarding claim 5, Mick in view of Phillips and Cannon discloses all the elements of the current invention, as applied to Claim 2, except for the shaft member being disposed parallel to the patient's face, and permitting rotation about the shaft, perpendicular to the patient's face.

Cannon further discloses that the shaft member is disposed in a direction parallel to the patient's face (Figure 1), thereby permitting rotation about it in a direction perpendicular to the patient's face (Figure 1), in order to increase the patient's comfort while wearing the apparatus. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Mick in view of Phillips and Cannon with the shaft member being disposed in a direction parallel to the patient's face and permitting rotation about the shaft in a direction perpendicular to the patient's face, as taught by Cannon, in order to increase the patient's comfort while wearing the apparatus.

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mick in view of Phillips and Cannon, as applied to claim 2 above, and further in view of Yang (US Patent 6739218).

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Mick in view of Phillips'637 and Cannon'816 discloses all the elements of the current invention except for the shaft member being formed of a flexible material and having a size no less than the size of the hole.

Cannon'816 further teaches forming the shaft member no smaller than the size of the hole (figures 1, 2, 5, 6), so the hinge moves securely.

Yang'218 teaches a device comprising a shaft member that fits into a hole to allow the device to pivot. Said shaft member (element 56) is formed of a flexible material (column 4, line 73), in order to increase the resilience of the component.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Mick in view of Phillips'637 and Cannon'816 with a flexible shaft, as taught by Yang'218, that is sized no smaller than its hole, as taught by Cannon'816, so that the components are resilient and the hinge moves securely.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mick in view of Phillips'637 as applied to claim 1 above, and further in view of Starr'049 (US Patent 6849049).

Regarding Claim 9, Mick in view of Phillips'637 discloses all the elements of the current invention as applied to Claim 1 above. Mick further discloses that the airway adapter comprises an inlet member adapted to be inserted into a nostril having a passage for guiding nasal expiration into the airway passage (elements 60). Mick in view of Phillips'637 does not disclose a vent hole.

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Starr'049 teaches a patient monitoring and sensing device comprising an inlet member (element 202) adapted to be inserted into a nostril having a passage for guiding nasal expiration into an airway passage (element 214) and a vent hole (element 212), so that excess expiration does not overwhelm the sensing system.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mick in view of Phillips'637 with a vent hole, as taught by Starr'049, so that excess expiration does not overwhelm the sensing system.

Allowable Subject Matter

5. Claims 10-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the structure of Claims 10-12, including, *inter-alia*, forming a vent hole at the junction between two tube inlet members that are adapted to be inserted into nostrils.

Response to Arguments

6. Applicant's arguments, see remarks, filed 2 October 2006, with respect to the rejection(s) of claim(s) 1-5, 9, and 17 under Star (US Patent Application Publication 2005/0245836) have been fully considered and are persuasive.

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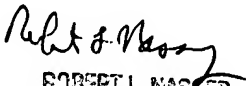
Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Mick.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ROBERT L. NASSER
PRIMARY EXAMINER

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